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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 7/2/96

SUBJECT: ID# ID960002 & ID960003 **SECTION 24(C) SPECIAL LOCAL
NEED REGISTRATIONS FOR USE OF DIDECYL DIMETHYL AMMONIUM
CHLORIDE AND/OR CHLORINE DIOXIDE ON POTATO CUTTING
EQUIPMENT IN THE STATE OF IDAHO.**

DP Barcode: D226658, D226677

Trade Names: Agricide-20 and Anthium Dioxide

Chem#: 020503, 069149

Caswell: 179A, 331A

Reg#: 10589-4, 9150-2

Case#: 46404, 46396

Class: Biocide/Fungicide

TO: Robert Travaglini
Antimicrobial Branch/RD (7505C)

FROM: *Tina Manville*
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THRU: Michael S. Metzger, Acting Chief
RCAB/HED (7509C)

A handwritten signature in dark ink, appearing to read "Michael S. Metzger".

INTRODUCTION

The State of Idaho has issued Special Local Need (SLN) registrations (Section 24(c)) for the use of Anthium Dioxide (5% chlorine dioxide) or Agricide-20 (0.72% chlorine dioxide and 0.40% didecyl dimethyl ammonium chloride) on potato seed cutting equipment during operation and potato seed pieces after cutting for the control of various diseases. Both products are currently registered for disinfection uses at various institutional and industrial sites. There are no federally registered food/feed uses for chlorine dioxide or didecyl dimethyl ammonium chloride.

RECOMMENDATION

PIRAT recommends against the issuance of these SLN registrations for the following reasons:

1) 40 CFR §162.152 (a)(2) states that for a Section 24(c) registration, the use must be covered by necessary tolerances, exemptions or other clearances under the FFDCA (21 U.S.C. 346 et seq.), if the use is a food or feed use. The SLN labels permit direct treatment of potatoes during seed cutting operations and treatment of the pile of seed pieces after cutting. The Agency considers seed treatments to be a food use. There are no tolerances or exemptions from the requirements for tolerances for residues of chlorine dioxide or didecyl dimethyl ammonium chloride in/on potatoes. Therefore, Section 24(c) registrations are not permissible for these uses.

2) Worker Margins of Exposure exceed HED's level of concern.

CONCLUSIONS

Hazard Assessment

1. Occupational Exposure Endpoint Selection

- a) Short-Term Risk for chlorine dioxide. For short-term dermal MOE calculations, the ad hoc TES (toxicology chemical reviewer, Toxicology Branch Chief, SAB Chief) Committee recommended use of the developmental NOEL of 10 mg/L (0.5 mg/kg/day) from a developmental toxicity drinking water study in rats (MRID #40943904A). At the LEL of 100 mg/L (5 mg/kg/day), there were decreased implants and decreased live fetuses.
- b) Short-Term Risk for didecyl dimethyl ammonium chloride. For short-term dermal MOE calculations, the ad hoc TES Committee recommended use of the NOEL of >12 mg/kg/day (HDT) from the 3-month dermal study in rat (MRID # not available). No LEL was established.
- c) Chronic and Intermediate-Term Risk. There is no chronic or intermediate-term worker exposure scenario for either of these uses and no toxicity endpoints were selected.
- d) Cancer Risk. Neither chlorine dioxide nor didecyl dimethyl ammonium chloride have been classified as to their oncogenicity by the Agency's peer review committee.
- e) Dermal Penetration. The default value of 100% is being used for dermal penetration in the absence of actual

data.

Worker Exposure

1. Acute data for these end-use products were not provided to PIRAT. The labels for Anthium Dioxide and Agricide-20 do not list any personal protective equipment (PPE) for agricultural handlers. Because these disinfectants are being applied to potato seed pieces, these uses are seed treatments. PIRAT considers these types of seed treatments part of the process of producing agricultural crops. Therefore, these uses fall under the scope of the Worker Protection Standard (WPS). **The labels need to be amended to be in compliance with the WPS (see PR Notice 93-7: Notice to Manufacturers, Formulators, Producers, and Registrants of Agricultural Pesticides, April 20, 1993).**
2. Acute data for the technical products are available. A restricted entry interval (REI) is not applicable for these uses.
3. Occupational exposure assumptions and estimates are summarized in Tables 1, 2, and 3. Allowing continuous applications of 10% solutions of Agricide-20 or 3% solutions of Anthium Dioxide to potato seed cutter blades during the potato cutting operations increases worker exposure considerably over previous registered uses. **Margins of exposure (MOEs) exceed HED's level of concern for chlorine dioxide in both products (MOEs = 15 and 29 for Anthium Dioxide and Agricide-20, respectively) even when gloves and chemical-resistant coveralls are worn over a single layer of clothes.**
4. **PIRAT's worker exposure assessment is based on many assumptions which may not be representative of a worst case scenario.** The product labels do not contain detailed application instructions such as boom or nozzle calibration, nozzle pressure, or rate of application. Both labels state apply by hand or mechanical sprayer positioned over the cutting equipment and or potato pile. The Pesticide Handlers Exposure Database (PHED) does not contain data for this exposure scenario (application by mechanical sprayer positioned above a large object such as potato cutting equipment). The closest exposure scenario in PHED is for mixers/loaders/applicators using low pressure hand wand. It is unclear whether the exposure from a mechanical sprayer would be greater or less than application by low pressure hand wand. Additionally, there are no dermal penetration data available for chlorine dioxide so 100% dermal absorption was assumed.

Dietary Exposure

Food/Non-Food Use Determination

In the absence of established tolerances or exemptions from tolerances, these uses must qualify as non-food uses in order to gain approval under Section 24(c). According to the *Pesticide Assessment Guidelines, Subdivision O* §171-12(a), in order for a seed treatment use to be considered a non-food use, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the plant. In this case, because potato tubers are the edible portion of the plant, no uptake of radioactivity into the tubers will have to be demonstrated for HED to consider these non-food uses.

Because residues could occur in food or feed, the requested uses are food uses and tolerances or exemptions from tolerances are required in order to issue Section 24(c) registrations.

SUPPLEMENTAL INFORMATION

Occupational Exposure

Table 1. Occupational Exposure Assumptions	
PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From Best Available Surrogate Exposure Table (BASET, 5/29/96)	Mixer/Loader /Applicator for low pressure hand wand: Dermal = 103.8 mg/lb ai handled, Inhalation = 31.2 µg/lb ai handled
Work Clothing and PPE	Single layer, no gloves
Percent Absorption	Dermal: 100% (default)
Application Type	Low pressure hand wand
Finish Spray	For Anthium dioxide: a 1:33 dilution (chlorine dioxide 0.15% ai) For Agricide-20: a 1:10 dilution (chlorine dioxide 0.072% ai, didecyl dimethyl ammonium chloride 0.04% ai)

Table 1. Occupational Exposure Assumptions	
PARAMETER	ASSUMPTION
Maximum Application Rate	For Anthium dioxide: chlorine dioxide 0.015 lb ai/gal For Agricide-20: chlorine dioxide 0.0072 lb ai/gal, didecyl dimethyl ammonium chloride 0.0043 lb ai/gal
Gallons Applied/Day	40 gal (default)
Average Farm Size (1992 Ag Census)	Based on state of Idaho data: 230 acres
Worker Weight	60 kg for chlorine dioxide calculations, 70 kg for didecyl dimethyl ammonium chloride calculations (both based on Tox endpoints)

Further information on the application scenario was obtained from a conversation with George Robinson from the Idaho Department of Agriculture (208-332-8593). The potato cutting machine used to produce seed pieces is a large piece of mobile equipment. Potatoes that have been stored for the winter move along a conveyor belt and pass under blades (up to 5 feet wide) which slice them into pieces for planting. After cutting, the potato pieces enter the cut seed conveyor where they drop into a pile or container. The cutting can take place in the farmer's potato storage building or outside next to the field. Practices vary among farmers but they could have the machinery running up to 12 hours a day. After the potatoes are cut, they can be planted immediately or stored for a couple of days. The State of Idaho would like the farmers to be able to apply a disinfectant continuously to the cutting blades during potato cutting operations and directly to the pile of cut potato seed pieces (i.e. a seed treatment use).

The most probable application method would be a boom with nozzles positioned above the cutting blades with solutions sprayed at about 40 psi. Workers would be around the machinery ensuring smooth operation and could handle the potatoes after they are sliced into seed pieces.

Table 2. Mixer/Loader/Applicator Exposure and Risk Assessment to Anthium Dioxide.				
Active Ingredient	Clothing Scenario	Dermal Unit Exposure^a (μg/kg/day)	Average Dermal Daily Dose^b (ug/kg/day)	Short-Term Dermal MOE^c
Chlorine Dioxide 5% Formulation	single layer	103,800	1,038	0.48
	single layer plus gloves	4,100	41	12
	coveralls over a single layer plus gloves	3,400	34	15

^a From the Best Available Surrogate Exposure Table (BASET, 5/29/96) derived from PHED. The protection that chemical-resistant coveralls would provide was arithmetically calculated by reducing the exposure to the affected body parts by 50%. **Since the inhalation unit exposure is less than 1% of the total unit exposure, the inhalation daily dose will not be calculated.**

^b Average Daily Dose (ADD) = PHED unit exposure x % absorption x application rate x gallons used/day ÷ kg body weight.

^c Short-Term Occupational Exposure MOE = NOEL/ADD (where NOEL = 0.5 mg/kg/day). MOEs are expressed to two significant figures.

Table 3. Mixer/Loader/Applicator Exposure and Risk Assessment to Agricide-20.				
Active Ingredient	Clothing Scenario	Dermal Unit Exposure^a (μg/kg/day)	Average Dermal Daily Dose^b (ug/kg/day)	Short-Term Dermal MOE^c
Chlorine Dioxide 0.72% Formulation	single layer	103,800	505	1
	single layer plus gloves	4,100	20	25
	coveralls over a single layer plus gloves	3,400	17	29

Table 3. Mixer/Loader/Applicator Exposure and Risk Assessment to Agricide-20.				
Active Ingredient	Clothing Scenario	Dermal Unit Exposure^a (μg/kg/day)	Average Dermal Daily Dose^b (ug/kg/day)	Short-Term Dermal MOE^c
Didecyl Dimethyl Ammonium Chloride 0.40% Formulation	single layer	103,800	255	47
	single layer plus gloves	4,100	10	1,200
	coveralls over a single layer plus gloves	3,400	N/A ^d	N/A ^d

^a From the Best Available Surrogate Exposure Table (BASET, 5/29/96) derived from PHED. The protection that chemical-resistant coveralls would provide was arithmetically calculated by reducing the exposure to the affected body parts by 50%. **Since the inhalation unit exposure is less than 1% of the total unit exposure, the inhalation daily dose will not be calculated.**

^b Average Daily Dose (ADD) = PHED unit exposure x % absorption x application rate x gallons used/day ÷ kg body weight.

^c Short-Term Occupational Exposure MOE = NOEL/ADD (where NOEL for chlorine dioxide= 0.5 mg/kg/day & NOEL for didecyl dimethyl ammonium chloride = 12 mg/kg/day). MOEs are expressed to two significant figures.

^d MOE and daily dermal dose were not calculated for this clothing scenario, since the MOE for a single layer plus gloves is over 100.

Dietary Exposure

Table 4. Residue Consideration Summary Table	
PARAMETER	PROPOSED USE
CHEMICAL	Agricide-20: Chlorine Dioxide (0.72%) and Didecyl Dimethyl Ammonium Chloride (0.4%) Anthium Dioxide: Chlorine Dioxide (5%)
FORMULATION	Agricide-20 (EPA Reg. No. 10589-4, Pettibone Labs. Inc.) Anthium Dioxide (EPA Reg. No. 9150-2, Pettibone Labs. Inc.)
CROP	Potato seed treatment - Seed cutter, cutting operations, handling, equipment and storage cellar use.

Table 4. Residue Consideration Summary Table

PARAMETER	PROPOSED USE
TYPE APPLICATION	Apply so that all surface areas are thoroughly moistened (with a 1:10 dilution for Agricide-20 or 1:33 dilution for Anthium Dioxide) by use of a hand or mechanical sprayer positioned over the belt or pile after cutting . Thoroughly clean and sanitize cutting machines, knives, trays, barrels, equipment, trucks and planters before cutting.
# APPLICATIONS	As needed for cutting operations
RATE/APPLIC.	1:10 dilution of Agricide-20 results in solution containing chlorine dioxide at 0.072% and didecyl dimethyl ammonium chloride at 0.04%. A 1:33 dilution of Anthium Dioxide results in solution containing chlorine dioxide at 0.15%.
MAXIMUM RESIDUE	N/A
RESTRICTIONS	Do not use treated potato seed pieces for food, feed, or fodder. Do not cut, treat, and pile for extended periods. Plant as soon as possible after cutting and treating.
RESIDUE DATA SOURCE	No residue data were supplied with this submission.
PERFORMING LAB	N/A

Additional Information

Based on information available in Agricultural Statistics (USDA, 1993), for the years 1991-1993 the average yield per acre for potatoes grown in ID was approximately 31,000 lbs. Information obtained from Potato Production in the Northeast (University of Massachusetts Cooperative Extension, 1986) stated that the fresh weight of potato foliage is approximately 50,000 lbs/A at plant maturity. The total plant mass produced from an acre of potato plants is therefore approximately 80,000 lbs.

Information provided in Potatoes - Fruit and Vegetables Facts and Pointers (US Fresh Fruit Assoc., August 1972, R.A.Seelig), stated that, "In dryland potato production in the Western states, the distance between rows is usually 42 inches and the seed pieces are spaced 14 to 30 inches apart in the row. The quantity of potatoes needed to plant an acre depends on spacing and size of potato pieces, and ranges from 1000 to 2200 pounds per acre." Seed pieces weigh from 1 to 2 oz. each.

Using an average of 1600 lb seed pieces/A yielding an average of 80,000 lbs plant material/A, a growth dilution factor of 1:50 is obtained.

If potato seed pieces (1.5 oz) absorb 10% of their weight of the sanitizing solution (0.15 oz solution), approximately 60 ppm of ClO_2 and 34 ppm of didecyl dimethyl ammonium chloride would be present in/on the seed piece (after treatment with Agricide-20) as follows:

1.5 oz seed piece x 28.3 g/oz = 42.5 g seed piece (plus weight of absorbed solution (4.3 g) equals approximately 50 g or 0.05 kg

$\frac{0.07 \text{ g } \text{ClO}_2}{100 \text{ ml solution}} \times 4.3 \text{ ml solution absorbed by seed piece} = 0.003 \text{ g } \text{ClO}_2$

$\frac{3 \text{ mg } \text{ClO}_2}{0.05 \text{ kg seed piece}} = 60 \text{ ppm } \text{ClO}_2$

For Anthium Dioxide, using the assumptions presented above, and the 1:33 dilution indicated on the label (not 10% which should be removed), approximately 120 ppm ClO_2 would be present in/on a seed piece.

The 10% absorption factor for the sanitizing solution was estimated based on the percent dry matter of potato tubers being 20% (Table II, September 1995).

Applying a 50-fold dilution factor to 120 ppm ClO_2 results in a residue level of about 2 ppm in/on potato plants. Because residues could occur in food or feed, the requested uses are food uses and tolerances or exemptions from tolerances are required in order to issue the Section 24(c) registrations.

cc: T. Manville, S. Williams-Foy, S. Knizner, PIRAT, OREB (020503, 069149), Caswell File (179A, 331A), TOX II (E. Budd, L. Chitlik), CBTS (Sect 24c), RCAB (Paula Deschamp)

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